

SPF 40 BROAD SPECTRUM NON-TINTED- zinc oxide cream
Teton Dermatology Holdings, Inc.

DRUG FACTS (cont)

INACTIVE INGREDIENTS: C₁₂₋₁₅ Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogren Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

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307-734-1800
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**TETON
 DERMATOLOGY**

Medical, Surgical & Cosmetic Skin Care

SPF 40
Broad Spectrum

WATER RESISTANT (40 MINS)
FREE OF CHEMICAL SUNSCREENS

NET WT 4 OZ/115 G



DRUG FACTS

ACTIVE INGREDIENTS: Zinc Oxide 20%
PURPOSE: Sunscreen

USES: Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early aging caused by the sun.

WARNINGS: For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

DIRECTIONS:

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - Reapply at least every 2 hours
- Children under 6 months: Ask a doctor
- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 am- 2 pm
 - Wear long sleeve shirts and hats and sunglasses

SPF 40 BROAD SPECTRUM NON-TINTED

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85339-205(NDC:58892-205)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
TRIETHANOLAMINE (UNII: 9O3K93S3TK)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
WATER (UNII: 059QF0KO0R)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
GLYCERIN (UNII: PDC6A3C0OX)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
DIMETHICONE (UNII: 92RU3N3Y1O)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85339-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/27/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/27/2023	

Labeler - Teton Dermatology Holdings, Inc. (078310619)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85339-205)

Establishment

Name	Address	ID/FEI	Business Operations
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Fragrance Manufacturing Inc.		793406000	manufacture(85339-205)
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Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85339-205)

Revised: 12/2025

Teton Dermatology Holdings, Inc.